

K081849

7/16/08

510(k) Summary K08

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Contact: Chris Roerig
Date Prepared: May 16, 2008

1. Identification of the Device:

Proprietary-Trade Name: Amplivox Otowave 102 Hand Held Portable Tympanometer.

Classification Name: Tympanometer

Product Codes Tympanometer: NAS (new product code, no 510(k)s under this code)

Audiometer: EWO or Tester, auditory impedance ETY

Common/Usual Name: Tympanometer.

2. Equivalent legally marketed devices: K925585, GSI 38 AUTO TYMP LUCAS GRASON-STADLER, INC. and K060885 the Maico MI 44 Tympanometer. (Plus numerous others)..

3. Indications for Use (intended use) The Amplivox Otowave is designed for use by trained operators in hospitals, ENT clinics, and audiologist offices for the detection of possible otologic disorders associated with the functioning of the middle ear. The instrument performs two types of measurement: Tympanometry is used to measure the compliance of the tympanic membrane and middle ear at a fixed frequency over a range of pressures. Reflex tests are used to measure stapedial reflexes. The Otowave measures ipsilateral reflexes and, when selected, reflex measurement is automatically carried out after a tympanogram is taken.

4. Description of the Device: This is a hand held portable tympanometer. It features:

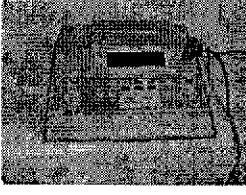
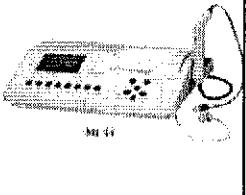
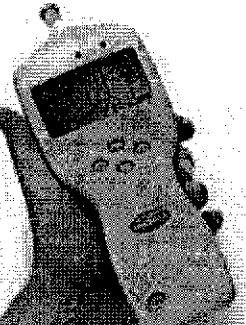
- Automatic measurement of ear canal volume, tympanic compliance peak, placement of the peak and the gradient.
- Automatic detection of stapedial reflexes.
- Up to 30, dual-ear patient tests can be stored in non-volatile memory.
- Configurable settings for user preferences, held in non-volatile memory.
- Printout via an infrared link to a thermal printer.
- Transfer to Windows XP via an infrared IrDA link for storage and display using NOAH..

5. Safety and Effectiveness, comparison to predicate device. The results of bench, user, and standards testing indicates that the new device is as safe and effective as the predicate devices.

6. Substantial Equivalence Chart (See next page)

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Item	K925585, GSI 38 AUTO TYMP LUCAS GRASON-STADLER, INC.	K060885 the Maico MI 44 Tympanometer.	Amplivox Otowave 102
Intended Use:	(Not found in FDA database) but inferred from classification: a device that is intended to change the air pressure in the external auditory canal and measure and graph the mobility characteristics of the tympanic membrane to evaluate the functional condition of the middle ear. The device is used to determine abnormalities in the mobility of the tympanic membrane due to stiffness, flaccidity, or the presence of fluid in the middle ear cavity. The device is also used to measure the acoustic reflex threshold from contractions of the stapedial muscle, to monitor healing of tympanic membrane grafts or stapedectomies, or to monitor followup treatment for inflammation of the middle ear.	The Maico Diagnostics model MI 44 tympanometer is intended for use by trained operators in hospitals, ENT clinics and audiologist offices for the detection of possible otologic disorders associated with the functioning of the middle ear. This is accomplished by measuring the acoustic impedance of the ear canal under various conditions.	The Amplivox Otowave is designed for use by trained operators in hospitals, ENT clinics, and audiologist offices for the detection of possible otologic disorders associated with the functioning of the middle ear. The instrument performs two types of measurement: Tympanometry is used to measure the compliance of the tympanic membrane and middle ear at a fixed frequency over a range of pressures. Reflex tests are used to measure stapedial reflexes. The Otowave measures ipsilateral reflexes and, when selected, reflex measurement is automatically carried out after a tympanogram is taken.
User Interface	LCD	LCD	LCD
Form factor	Desktop 	Desktop 	Handheld 
Power source	120 Vac	100 - 240 V / 50/60 Hz	Battery Operated
Safety	Specification not found.	IEC 601-1 (EN 60601-1).	UL and IEC 60601-1

7. Conclusion After analyzing bench, user, and standards testing data, it is the conclusion of Amplivox Ltd. that the Otowave 102 Tympanometer is safe and effective as the predicate devices, has few technological differences, and have no new indications for use, thus rendering them substantially equivalent to the predicate devices



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Amplivox Ltd.
c/o James W. Monroe
Intertek Testing Services NA, Inc.
2307 E. Aurora Rd., Unit B7
Twinsburg, OH 44087

JUL 16 2008

Re: K081841

Trade/Device Name: Amplivox Otowave 102 Hand Held Portable Tympanometer
Regulation Number: 21 CFR 874.1090
Regulation Name: Auditory Impedance Tester
Regulatory Class: Class II
Product Code: ETY
Dated: June 27, 2008
Received: June 30, 2008

Dear Mr. Monroe:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear, Nose
and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K081841

Indications for Use

510(k) Number (if known): _____

Device Name: Amplivox Otowave 102 Hand Held Portable Tympanometer.

Indications For Use:

The Amplivox Otowave is designed for use by trained operators in hospitals, ENT clinics, and audiologist offices for the detection of possible otologic disorders associated with the functioning of the middle ear. The instrument performs two types of measurement:

Tympanometry is used to measure the compliance of the tympanic membrane and middle ear at a fixed frequency over a range of pressures.

Reflex tests are used to measure stapedial reflexes. The Otowave measures ipsilateral reflexes and, when selected, reflex measurement is automatically carried out after a tympanogram is taken..

Prescription Use AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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(Division Sign-Off)
Division of Ophthalmic Ear,
Nose and Throat Devices
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